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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/678,580	10/03/00	JAPUNTICH	D 48317USA7K.0

EXAMINER	
LEWIS,A	
ART UNIT	**PAPER NUMBER**
3761	4

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/678,580	DANIEL A. JAPUNTICH ET AL.
Examiner	**Art Unit**
AARON J. LEWIS	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 3, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *33-65* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *33-65* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Double Patenting

1. Claims 33-65 of this application conflict with claims 34-77 of Application No. 08/240,877; 34-77 of 09/440,619; 33-62 of 09/678,579; 33-61 of 09/678,488; 33-56 of 09/677,637; 33-64 of 09/677,636. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "...surface [of the valve cover] that mechanically holds the flexible flap against the flap-retaining surface..." must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Objections

3. Claim 62 is objected to because of the following informalities: it is recited to depend from itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 33-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 33, "...that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface." is not disclosed in the specification nor is such an arrangement illustrated in the drawings.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 33-36,50-56,58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of French patent 1,209,475.

As to claim 33, Simpson et al. disclose a filtering face mask that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer (fig.1); and an exhalation valve (fig.2)

that is attached to the mask body, the exhalation valve comprising: a seal surface; an orifice (16) that is circumscribed by the seal surface; and a flap-retaining surface (portion abutting retainer 17); and a single flexible flap (15) that has a fixed portion and a free portion and first and second opposing ends (fig.2), the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during exhalation, and the second end being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice (page 2, lines 37-50).

The difference between Simpson et al. and claim 33 is a valve cover that is disposed over the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface.

French patent ('475) teaches a valve cover (#2 of figs.3 and 4) disposed over (11,34) the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap retaining surface (15).

It would have been obvious to modify the valve of Simpson et al. to employ a cover because it would have provided protection for the exhalation valve and because it would have provided a means for accessing the valve for cleaning and/or replacement as taught by as taught by French patent ('475).

As to claims 34 and 35, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including plastic material. It is noted that Simpson (page 2, line 39) discloses the valve flap being made from a plastic material. It is submitted that it would have been obvious to make the valve seat from any well known material including a plastic material because it would physically cooperate more effectively with a valve flap of the same material rather than one made from a different material.

As to claim 36, the seal (figs.2) of Simpson et al. is illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed of being made from plastic and since known physical characteristices of plastics include flexibility and resiliency, it would have been obvious that the flap (15) of Simpson et al. being made from plastic is "...capable of allowing the flap to display a bias towards the seal surface.".

As to claim 50, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts.

As to claim 51, the flange against which the valve flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

As to claim 52, given the downward orientation of the mask body (1,2) of Simpson et al. fig.1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body the

of mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig.1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 53, the mask body of Simpson et al. is cup shaped and includes at least one shaping layer and a filtration layer (page 1, lines 108-123). Simpson et al. (page 1, line 116) disclose that the shaping layer may be located on one or both sides of the filtration layer. One or both sides would include being located outside of the filtration layer.

As to claims 54-56, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, it would have been obvious that the valve would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 58, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on wearer's face, the valve (fig.2) mounted in cantilever fashion on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1).

As to claim 59, the exhalation valve (fig.2) of Simpson et al. as modified by French patent ('475) teach the flexible flap being held in position between the valve seat and the valve cover by mechanical clamping (35).

As to claim 60, the orifice of Simpson et al. as modified by French patent ('475) as illustrated does not wholly correspond to the shape of the seal surface inasmuch as the orifice is surrounded by the seal surface.

8. Claims 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of French patent 1,209,475 as applied to claims 33-36,50-56,58-60 above, and further in view of McKim.

The difference between Simpson et al. as modified by French patent 1,209,475 and claim 37 is the flexible flap having a curved profile.

McKim ('618) teaches a valve flap having a fixed portion (14a) and a free portion (opposite the fixed portion as illustrated in figs.1 and 3), the one free portion of the flexible flap having a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface. McKim teaches a curved seal surface and curved flexible flap for the purpose of seating quickly, effectively and without float or bounce after each opening (col.1, lines 64-72).

It would have been obvious to modify the flexible valve flap and seat of Simpson et al.(fig.2) to be curved because it would have provided quick seating, in an effective manner and without float or bounce after each opening as taught by McKim.

As to claims 38-39, the flaps (15,14) of Simpson are disclsoed as being made from plastic and/or rubber, respectively. The physical characteristics of plastics and rubbers include elasticity.

Consequently, the particular material from which the valve flaps of Simpson et al. are made can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular elasticity of such a material.

As to claims 40 and 41, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one oridinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation and including a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 42-46,48,49, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency.

As to claim 47, the one free portion of the flexible flap (see fig.3 of McKim) of Simpson et al. as modified by McKim has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

9. Claims 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of French patent ('475) as applied to claims 33-36,50-56,58-60 above, and further in view of Courtney.

As to claim 61, the valve cover of French patent ('475) is illustrated in figs.3 and 4 to have an opening that is disposed directly in the path of fluid flow when a free portion of the flexible flap (14) is lifted from the seal surface during an exhalation; a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end.

The difference between Simpson et al. as modified by French patent ('475) and claim 61 is cross members that are disposed within the opening of the valve cover.

Courtney, in a filtering face mask, teaches a valve cover (3) that is disposed over the valve seat and that comprises: an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation; a fluid impermeable ceiling (the material of cross members (19) is fluid impermeable) that increases in height in the direction of the flexible flap from the first end to the second end; and cross members (19) that are disposed within the opening of the valve cover for the purpose of protecting the valve and valve opening (col.2, lines 8-11).

It would have been obvious to modify the valve of Simpson et al. to employ a cover having a ceiling because it would have provided protection for the exhalation valve as taught by Courtney.

As to claim 62, the valve cover of French patent ('475) is illustrated in figs.3 and 4 as being approximately parallel to the path traced by the second end of the flexible flap (14) during its opening and closing.

As to claim 63, Simpson et al. as further modified by French patent ('475) teach a cover which is fully capable performing the recited function of directing exhaled air downwards when the mask is worn by a person.

As to claim 64, the cover of French patent (figs.3 and 4) illustrates fluid-impermeable sidewalls.

As to claim 65, the opening in the cover of French patent ('475) is at least the size of the orifice in the valve seat as illustrated in figs.3 and 4.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant filtering face mask having exhalation valves.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

July 1, 2001

Aaron J. Lewis
Primary Examiner